

### AMENDMENT OF THE CLAIMS

Please amend the claims as follows. This listing of claims will replace all prior versions and listings of claims in the application.

1. (Withdrawn) (Canceled)
2. (Withdrawn) (Currently amended) A method for inducing cell death in prostate cancer cells, the method comprising treating androgen responsive and androgen independent prostate cancer cells with an effective amount of ~~TRAIL~~ a Tumor necrosis factor  $\alpha$  - Related Apoptosis Inducing Ligand (TRAIL) polypeptide comprising the amino acid sequence SEQ ID NO: 1 and an effective amount of an antiprogesterin, such that the combination of the TRAIL and the antiprogesterin ~~sufficient to induce~~ induces apoptosis in at least a portion a greater number of the treated cancer cells than the additive effect of TRAIL and the antiprogesterin separately applied to the cancer cells.
3. (Withdrawn) The method of claim 2, wherein the antiprogesterin comprises Mifepristone.
4. (Withdrawn) (Currently amended) A method for treating prostate cancer by inducing cell death in cancer cells, the method comprising treating androgen responsive and androgen independent prostate cancer cells with a pharmaceutical composition comprising an effective amount of ~~TRAIL~~ a Tumor necrosis factor  $\alpha$  - Related Apoptosis Inducing Ligand (TRAIL) polypeptide comprising the amino acid sequence SEQ ID NO: 1 and an effective amount of Mifepristone, such that the combination of the TRAIL and the Mifepristone ~~sufficient to induce~~ induces apoptosis in at least a portion a greater number of the treated cancer cells than the additive effect of TRAIL and the Mifepristone applied to the cancer cells.
5. (Withdrawn) (Currently amended) The method of claim 4, wherein the cancer cells are treated with Mifepristone prior to being treated with TRAIL polypeptide.

6. (Withdrawn) (Currently amended) The method of claim 4, wherein the cancer cells are treated with Mifepristone and TRAIL polypeptide concurrently.
7. (Withdrawn) (Currently amended) The method of claim 4, wherein the dose of TRAIL polypeptide in ~~said~~ the pharmaceutical composition results in a local concentration of TRAIL polypeptide at the prostate cancer tumor which ranges from 1 to 1,000 ng/ml.
8. (Withdrawn) (Currently amended) The method of claim 4, wherein the dose of TRAIL polypeptide in ~~said~~ the pharmaceutical composition results in a local concentration of TRAIL polypeptide at the prostate cancer tumor which ranges from 200 to 600 ng/ml.
9. (Withdrawn) (Currently amended) The method of claim 4, wherein the dose of TRAIL polypeptide in ~~said~~ the pharmaceutical composition results in a local concentration of TRAIL polypeptide at the prostate cancer tumor which ranges from 350 to 450 ng/ml.
10. (Withdrawn) (Currently amended) The method of claim 4, wherein the dose of Mifepristone in ~~said~~ the pharmaceutical composition results in a local concentration of Mifepristone at the prostate cancer tumor which ranges from 1 to 1,000  $\mu$ M.
11. (Withdrawn) (Currently amended) The method of claim 4, wherein the dose of Mifepristone in ~~said~~ the pharmaceutical composition results in a local concentration of Mifepristone at the prostate cancer tumor which ranges from 1 to 100  $\mu$ M.
12. (Withdrawn) (Currently amended) The method of claim 4, wherein the dose of Mifepristone in ~~said~~ the pharmaceutical composition results in a local concentration of Mifepristone at the prostate cancer tumor which ranges from 5 to 20  $\mu$ M.
13. (Canceled)

14. (Canceled)

15. (Canceled)

16. (Withdrawn) (Currently amended) The method of claim 4, wherein the treatment of the cancer cells with TRAIL polypeptide and Mifepristone is associated with an increase in at least one death receptor in at least a portion of the treated androgen responsive and androgen independent prostate cancer cells.

17. (Withdrawn) (Currently amended) The method of claim 16, ~~further~~ comprising an increase in the death receptor DR4 and/or DR5.

18. (Withdrawn) (Currently amended) The method of claim 4, wherein the treatment of cancer cells with TRAIL polypeptide and Mifepristone is associated with an increase in an activated caspase enzyme enzymes in at least a portion of the treated androgen responsive and androgen independent prostate cancer cells.

19. (Withdrawn) (Currently amended) The method of claim 18, wherein the said activated ~~caspases comprise~~ caspase enzyme comprises at least one of caspase-8, caspase-7, caspase-9, or caspase-3.

20. (Withdrawn) (Currently amended) The method of claim 4, wherein the treatment of cancer cells with TRAIL polypeptide and Mifepristone is associated with an increase in truncated BID protein (tBid) in at least a portion of the treated androgen responsive and androgen independent prostate cancer cells.

21. (Withdrawn) (Currently amended) The method of claim 4, wherein the treatment of cancer cells with TRAIL polypeptide and Mifepristone is associated with a reduction of mitochondrial cytochrome c in mitochondrial function in at least a portion of the treated androgen responsive and androgen independent prostate cancer cells.

22. (Withdrawn) (Currently amended) The method of claim 4, wherein the treatment of cancer cells with TRAIL polypeptide and Mifepristone results in an increase in apoptosome formation in at least a portion of the treated androgen responsive and androgen independent prostate cancer cells.

23. (Withdrawn) (Canceled)

24. (Withdrawn) (Canceled)

25. (Withdrawn) The method of claim 4, wherein the manner of treatment comprises intravenous injection of said pharmaceutical composition.

26. (Withdrawn) The method of claim 4, in combination with other means of treatment such as surgery, chemotherapy, or radiation therapy.

27. (Withdrawn) (Canceled)

28. (Currently amended) A composition for treating prostate cancer by inducing cell death in androgen responsive and androgen independent prostate cancer cells comprising an effective amount of a Tumor necrosis factor  $\alpha$  - Related ~~apoptosis~~ Apoptosis Inducing Ligand (TRAIL) polypeptide comprising ~~a wild-type TRAIL polypeptide having the~~ amino acid sequence SEQ ID NO: 1, ~~or the biological equivalent thereof,~~ and an antiprogestin in a pharmaceutical carrier, wherein an effective amount comprises sufficient TRAIL polypeptide and antiprogestin to induce apoptosis in at least a portion of ~~said~~ the androgen responsive and androgen independent prostate cancer cells exposed to ~~said~~ the composition, and wherein the combination of the TRAIL and the antiprogestin induces apoptosis in a greater number of the treated androgen responsive and androgen independent prostate cancer cells than the additive effect of TRAIL and the antiprogestin separately applied to the cancer cells.

29. (Original) The composition of claim 28, wherein the antiprogesterone comprises Mifepristone.

30. (Currently amended) A composition for treating prostate cancer by inducing cell death in androgen responsive and androgen independent prostate cancer cells comprising an effective amount of a Tumor necrosis factor  $\alpha$  - Related ~~apoptosis~~ Apoptosis Inducing Ligand (TRAIL) polypeptide comprising ~~a wild-type TRAIL polypeptide~~ having the amino acid sequence SEQ ID NO: 1, ~~or the biological equivalent thereof~~, and Mifepristone in a pharmaceutical carrier, wherein an effective amount comprises sufficient TRAIL polypeptide and Mifepristone to induce apoptosis in at least a portion of ~~said the~~ androgen responsive and androgen independent prostate cancer cells exposed to ~~said the~~ composition, and wherein the combination of the TRAIL and the Mifepristone induces apoptosis in a greater number of the treated androgen responsive and androgen independent prostate cancer cells than the additive effect of TRAIL and the Mifepristone separately applied to the cancer cells.

31. (Currently amended) The composition of claim 30, wherein ~~said the~~ the Mifepristone and ~~said the~~ the TRAIL polypeptide are packaged in such a manner that the ~~said~~ Mifepristone is at least partially released for application to the cancer prior to the release of the ~~said~~ TRAIL polypeptide.

32. (Currently amended) The composition of claim 30, wherein ~~said the~~ the Mifepristone and ~~said the~~ the TRAIL polypeptide are packaged in such a manner so as to be released substantially simultaneously.

33. (Currently amended) The composition of claim 30, wherein the dose of TRAIL polypeptide results in a local concentration of TRAIL polypeptide at the prostate cancer ~~tumor~~ which ranges from 1 to 1,000 ng/ml.

34. (Currently amended) The composition of claim 30, wherein the dose of TRAIL polypeptide results in a local concentration of TRAIL polypeptide at the prostate cancer tumor which ranges from 200 to 600 ng/ml.
35. (Currently amended) The composition of claim 30, wherein the dose of TRAIL polypeptide results in a local concentration of TRAIL polypeptide at the prostate cancer tumor which ranges from 350 to 450 ng/ml.
36. (Currently amended) The composition of claim 30, wherein the dose of Mifepristone results in a local concentration of Mifepristone at the prostate cancer tumor which ranges from 1 to 1,000  $\mu$ M.
37. (Currently amended) The composition of claim 30, wherein the dose of Mifepristone results in a local concentration of Mifepristone at the prostate cancer tumor which ranges from 1 to 100  $\mu$ M.
38. (Currently amended) The composition of claim 30, wherein the dose of Mifepristone results in a local concentration of Mifepristone at the prostate cancer tumor which ranges from 5 to 20  $\mu$ M.
39. (Canceled)
40. (Canceled)
41. (Canceled)
42. (Currently amended) A kit for pharmaceutical treatment of androgen responsive and androgen independent prostate cancer comprising:
- (a) a pharmacologically effective amount of a Tumor necrosis factor  $\alpha$  - Related ~~apoptosis~~ Apoptosis Inducing Ligand (TRAIL) polypeptide comprising a ~~wild-~~

~~type TRAIL polypeptide having the amino acid sequence SEQ ID NO: 1, or the biological equivalent thereof,~~ packaged in a sterile container;

(b) a pharmacologically effective amount of an antiprogesterin packaged in a sterile container;

(c) at least one aliquot of a pharmaceutical carrier; and

(d) instructions for application of ~~said~~ the TRAIL polypeptide and ~~said~~ the antiprogesterin to a patient having prostate cancer such that application of both the TRAIL and the antiprogesterin induces apoptosis in a greater number of the treated androgen responsive and androgen independent prostate cancer cells than the additive effect of applying TRAIL and the antiprogesterin to the cancer separately.

43. (Currently amended) The kit of claim 42, wherein the ~~said~~ antiprogesterin comprises Mifepristone.

44. (Canceled)

45. (Currently amended) The composition of claim 28, wherein an effective amount of the TRAIL polypeptide and antiprogesterin results in an increase in at least one death receptor in at least a portion of the treated androgen responsive and androgen independent prostate cancer cells.

46. (Previously presented) The composition of claim 45, wherein the death receptor is at least one of DR4 or DR5.

47. (Currently amended) The composition of claim 28, wherein an effective amount of the TRAIL polypeptide and antiprogesterin results in an increase in an activated caspase ~~enzyme~~ enzymes in at least a portion of the treated androgen responsive and androgen independent prostate cancer cells.

48. (Currently amended) The composition of claim 47, wherein ~~the said~~ activated caspase enzyme comprises at least one of ~~caspsases comprise~~ caspase-8, caspase-7, caspase-9, or caspase-3.
49. (Currently amended) The composition of claim 28, wherein an effective amount of the TRAIL polypeptide and antiprogestin results in an increase in truncated BID protein (tBid) in at least a portion of the treated androgen responsive and androgen independent prostate cancer cells.
50. (Currently amended) The composition of claim 28, wherein an effective amount of the TRAIL polypeptide and antiprogestin results in a reduction of mitochondrial cytochrome c in mitochondrial function in at least a portion of the treated androgen responsive and androgen independent prostate cancer cells.
51. (Currently amended) The composition of claim 28, wherein an effective amount of the TRAIL polypeptide and antiprogestin results in an increase in apoptosome formation in at least a portion of the treated androgen responsive and androgen independent prostate cancer cells.
52. (Currently amended) The composition of claim 28, wherein ~~said~~ the antiprogestin and ~~said~~ the TRAIL polypeptide are packaged in such a manner that ~~said~~ the antiprogestin is at least partially released for application to the cancer prior to the release of ~~said~~ the TRAIL polypeptide.